JS 44 (Rev. 12/12)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS
BARBARA WHITE and PATRICK WHITE

(b) County of Residence of First Listed Plaintiff York
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
David B. Dowling/Karen A. Salvemini, Rhoads & Sinon LLP, One S. Market Sq., 12th Fl., P.O. Box 1146, Harrisburg, PA 17108-1146; (717) 233-5731

DEFENDANTS
DEPUY ORTHOPAEDICS, INC., DEPUY, INC., JOHNSON & JOHNSON SERVICES, INC., and JOHNSON & JOHNSON, INC.

County of Residence of First Listed Defendant Kosciusko
(IN U.S. PLAINTIFF CASES ONLY)
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 2 U.S. Government Defendant
- ☒ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☒ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☒ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

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- ☐ 370 Other Fraud
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- ☐ 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☐ 6 Multidistrict Litigation

VI. CAUSE OF ACTION
Cite the U.S. Civil Statute under which you are filing *(Do not cite jurisdictional statutes unless diversity)*:
Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§331, 333
Brief description of cause:
Product liability action (total hip replacement)

VII. REQUESTED IN COMPLAINT: ☐ CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P. **DEMAND $** CHECK YES only if demanded in complaint: **JURY DEMAND:** ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY *(See instructions):* JUDGE _____ DOCKET NUMBER _____

DATE 11/14/2013 SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA

BARBARA WHITE and PATRICK WHITE, *Plaintiffs*,	:	
	:	Case No.:
v.	:	
	:	JURY TRIAL DEMANDED
DEPUY ORTHOPAEDICS, INC., DEPUY, INC., JOHNSON & JOHNSON SERVICES, INC., and JOHNSON & JOHNSON, INC., *Defendants*.	:	

COMPLAINT

NOW COME, Plaintiffs, Barbara White and Patrick White, by and through their attorneys, Rhoads & Sinon LLP, and file the within Complaint as follows:

INTRODUCTION

1. This products liability lawsuit seeks damages on behalf of Plaintiff, Barbara White, who was implanted with two (2) artificial hips that Defendants designed, developed, made, manufactured, marketed, promoted, sold, and distributed as the DePuy ASR™ XL Modular Acetabular Cup System and the DePuy ASR™ Hip Resurfacing System ("DePuy ASR"). The components of Plaintiff's DePuy ASR were defective and failed because, among other things, its acetabular shell – the metallic cup fitted into Plaintiff's hip socket or acetabulum – had a design flaw.

2. Furthermore, the DePuy ASR uses a metal acetabular cup which is shallower than other cups and more susceptible to failure, along with the fact that the use of the metal acetabular cup and metal femoral ball forced the rubbing of metal against metal.

3. As a result of the defective design of the DePuy ASR, Plaintiff was forced to undergo two (2) painful right and left hip implant revision surgeries.

4. Publicly available data shows that Plaintiff Barbara White's problems and the need for two (2) revision surgeries were common among those individuals who had received DePuy ASR implants and that Defendants had been fully aware that the DePuy ASR systems were defective.

5. Prior to the date of Plaintiff's initial right and left hip replacement surgeries, Defendants knew or should have known of the high rate of failure of the DePuy ASR as well as the complications arising from the implantation of the DePuy ASR, including the metal debris release and other complications.

6. Defendants actively concealed such information and failed to warn Plaintiff, her physician, or the medical community generally of these significant risks resulting from the use of the DePuy ASR.

7. On August 24, 2010, the DePuy ASR was recalled based on a high rate of revision surgeries resulting from the dangerous conditions created by the design defects of the DePuy ASR.

PARTIES

8. At all relevant times, Barbara White was a resident and citizen of the Commonwealth of Pennsylvania and currently resides at 10341 Brillhart Road, Glen Rock, Pennsylvania 17327.

9. At all relevant times, Patrick White, husband of Plaintiff Barbara White, was a resident and citizen of the Commonwealth of Pennsylvania and currently resides at 10341 Brillhart Road, Glen Rock, Pennsylvania 17327.

10. Defendant DePuy, Inc. is, and at all times relevant to this Complaint, was a corporation organized and existing under the laws of the State of Delaware with its principal place of business located at 700 Orthopaedic Drive, Warsaw, Indiana 46581. DePuy, Inc. is qualified to do business in Pennsylvania and does business in Pennsylvania and in York County, Pennsylvania.

11. Defendant DePuy, Inc.'s registered agent for service of process is The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

12. DePuy, Inc. is a subsidiary of Defendant Johnson & Johnson, Inc.

13. Defendant DePuy Orthopaedics, Inc. is, and at all times relevant to this Complaint, was an Indiana corporation with its principal place of business at 700 Orthopaedic Drive, Warsaw, Indiana 46851. DePuy Orthopaedics, Inc. does business in Pennsylvania and in York County, Pennsylvania.

14. Defendant DePuy Orthopaedics, Inc.'s registered agent for service of process is CT Corporation System, 251 East Ohio Street, Suite 1100, Indianapolis, Indiana 46204.

15. Defendant DePuy Orthopaedics, Inc. is a subsidiary of Defendant DePuy, Inc. and is qualified to do business in Pennsylvania.

16. Defendant Johnson & Johnson Services, Inc. is a corporation organized and existing under the laws of the State of New Jersey with its principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933.

17. Defendant Johnson & Johnson Services, Inc.'s registered agent for service of process is Johnson & Johnson, One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933.

18. Defendant Johnson & Johnson Services, Inc. is a subsidiary of Defendant Johnson & Johnson, Inc.

19. Defendant Johnson & Johnson, Inc. is a corporation organized and existing under the laws of the State of New Jersey with its principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933.

20. Defendant Johnson & Johnson, Inc.'s registered agent for service of process is Douglas K. Chin, One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933.

21. Defendant Johnson & Johnson, Inc. is the parent company of Defendants Johnson & Johnson Services, Inc. and DePuy, Inc.

22. At all times relevant to this action, Defendants DePuy Orthopaedics, Inc., DePuy, Inc., Johnson & Johnson Services, Inc., and Johnson & Johnson, Inc. developed, designed, manufactured, advertised, promoted, marketed, sold, and/or distributed the defective DePuy ASR Hip System and its components and specifically, the defective acetabular cup, throughout the United States.

23. At all times relevant to this action, Defendants and each of them were the agents, ostensible agents, co-conspirators, servants, employees, partners, joint venturers, franchisees, and alter-egos of the remaining Defendants and each of them; and each of them were at all times and places mentioned herein acting within the course and scope of such conspiracy, service, agency, employment, partnership, joint venture, and/or franchise.

JURISDICTION AND VENUE

24. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §1332(a) because Plaintiff and Defendants are citizens of different states and the amount in controversy exceeds $150,000.00 exclusive of interest and costs.

25. Venue in this action properly lies in the Middle District of Pennsylvania pursuant to 28 U.S.C. §§1391(a) and (c), as a substantial number of the events, actions or omissions giving rise to Plaintiffs' claims occurred in this District. At all times material hereto, Defendants conducted substantial business in the Commonwealth of Pennsylvania.

26. At all times relevant to this action, Defendants were present and transacted, solicited, and conducted business in Pennsylvania, through their employees, agents, and/or sales representatives, and derived substantial revenue from such business.

27. At all times relevant to this action, Defendants placed the defective devices into the stream of interstate commerce that were surgically implanted in Plaintiff Barbara White in the Commonwealth of Pennsylvania.

28. Defendants Johnson & Johnson Services, Inc. and Johnson & Johnson, Inc. are organized and exist in the State of New Jersey, and their principal place of business is located in the State of New Jersey. At all times relevant to this

action, Defendants expected or should have expected that their acts and omissions would have consequences within the United States and the Commonwealth of Pennsylvania.

BACKGROUND ON ARTIFICIAL HIPS

29. This products liability lawsuit seeks damages on behalf of Plaintiff Barbara White, who was implanted with two (2) DePuy ASR artificial hip replacements designed, manufactured, marketed, distributed, and sold by Defendants.

30. The hip joint connects the thigh (femur) bone of a patient's leg to the patient's pelvis and is made of two parts: a ball and a socket. The c-shaped socket part of the hip is called the acetabulum while the femoral head at the top of the femur bone (the ball) rotates within the curved socket of the acetabulum. Over time, the cartilage surrounding the ball wears down, often resulting in the need for a total hip replacement involving the implanting of an artificial hip.

31. A total hip replacement replaces the body's natural joint with an artificial one, usually comprised of four components, including a femoral stem, a femoral head, a liner, and an acetabular shell.

32. The DePuy ASR belongs to a small category of devices known as metal-on metal implants, which are comprised of three components: the metal

femoral stem that is inserted into the femur, the metal femoral head (or ball) that connects to the stem and then fits inside the metal acetabulum cup (or socket).

33. The DePuy ASR hip replacement design puts the metal femoral ball directly in contact with the metal acetabular cup, which produces a large amount of metal on metal wear debris.

HISTORY OF DEPUY ASR

34. On or about December 4, 2003, the first components of the DePuy ASR were approved for use by the Food and Drug Administration ("FDA") through a process established in Section 510(k) of the Food, Drug, and Cosmetic Act and referred to as the "Section 510(k) Approval Process," which allows a medical device to gain approval by the FDA without the rigors of a clinical study based on the assertion that the new device, the DePuy ASR, demonstrated substantial equivalence to a predicate medical device.

35. No clinical trials were conducted in connection with the submission of the application to the FDA for the DePuy ASR as Defendants repeatedly asserted that the DePuy ASR was a device similar to previously approved predicate devices.

36. On August 5, 2005, the FDA cleared the DePuy ASR device for marketing and distribution in the United States.

37. In December 2009, the DePuy ASR was pulled from the Australian market.

38. In March 2010, Pamela L. Plouhar, then Vice President of Worldwide Clinical Affairs for DePuy, issued an "Urgent Field Safety Notice" to surgeons concerning a high amount of revisions of those individuals who had received DePuy ASR implants but failed to recall the device.

39. In May 2010, a Medical Device Alert was issued by the Medicines and Healthcare Products Regulatory Agency ("MBRA").

40. In July 2010, the FDA notified the public through its website that it was issuing a Class 2 recall of many of the DePuy ASR components.

41. Not until August 24, 2010 did DePuy issue a Voluntary Recall Notice of all DePuy ASR hip implant products due to high rates of hip implant failures.

42. On or about August 26, 2010, DePuy issued a press release concerning the recall of the various DePuy ASR components, citing higher than usual revision rates.

43. Due to the design of the DePuy ASR, the DePuy ASR can generate large amounts of metallic debris over time, eventually spreading this debris throughout the patient's surrounding bones and tissues.

44. The release and spreading of the metallic debris from the DePuy ASR can cause severe inflammatory responses, damage to muscles and tissue, pain, lack of mobility, and often requires subsequent revision surgery shortly after the implant to replace the implant instead of the fifteen or more years the artificial implant is expected to last.

45. The DePuy ASR's design flaw may also have made it more difficult for surgeons to implant the DePuy ASR properly.

46. The DePuy ASR's co-developer, Dr. Thomas P. Schmalzried, has indicated that during at least a two year period while the DePuy ASR continued to be implanted into patients, he, along with DePuy officials, recognized that the DePuy ASR was more challenging for surgeons to implant properly than other competing cups.

47. Furthermore, in addition to being more shallow than comparable implants and therefore more difficult to implant properly, the DePuy ASR also had a higher failure rate than most metal-on-metal implants.

48. Unpublished data from the National Joint Registry ("NJR") of England and Wales shows that a five year revision rate for the DePuy ASR as of 2010 was approximately twelve to thirteen percent. Defendants have acknowledged that under generally acceptable standards, no more than five percent

of patients should have a revision surgery within five years of implantation. The data released from NJR shows that the DePuy ASR had a revision rate more than double that of the generally acceptable standards.

49. Defendants aggressively marketed the DePuy ASR, indicating that it had many advantages over other hip replacement or hip resurfacing systems. The DePuy ASR was described by Defendants as a "high performance hip replacement" and was advertised with pictures of physically active individuals.

50. Defendants further advertised the DePuy ASR as a superior option, indicating that "[i]f you have gradually stopped doing the things you enjoy or are adapting your life to cope with reduced mobility hip replacement surgery may be appropriate for you."

51. Despite Defendants' aggressive marketing campaign, Defendants had knowledge of the DePuy ASR's high rate of failure for at least two years, perhaps even longer.

52. For more than two years prior to the August 2010 recall, the FDA had received numerous complaints that the DePuy ASR failed early in some patients due to issues such as component loosening, component malalignment, dislocation, and fracture, due to the design of the device. In addition, reports were received that the ball and socket components creating the new hip joint generated metal

debris over time from wear which could spread throughout the surrounding bone tissue and cause severe inflammation, damage, and blood poisoning. In the United States alone, since the beginning of 2008, the FDA has received at least four hundred complaints involving the DePuy ASR and the need for subsequent revision surgeries.

53. Prior to, on, and after December 4, 2008, Defendants knew that the DePuy ASR was defective and harmful to consumers and that the DePuy ASR had an unacceptably high failure and complication rate.

54. Defendants had an obligation to stop selling the DePuy ASR and to notify physicians who had implanted the DePuy ASR to be aware of the propensity for the DePuy ASR to fail and for some patients to develop adverse reactions to high levels of metal debris generated by normal use of the DePuy ASR.

PLAINTIFF'S INJURIES DUE TO THE DEFECTIVE DEPUY ASR

55. Plaintiff Barbara White, a 61 year old woman from York County, Pennsylvania, and her husband, Patrick White, have been significantly injured due to the implantation of two (2) DePuy ASRs in Plaintiff Barbara White's right and left hips.

56. As a result of the DePuy ASR's failure, Plaintiffs have had to adjust their lives to accommodate Ms. White's significant and ongoing injuries.

57. On or about August 31, 2008, Plaintiff Barbara White had the DePuy ASR implanted into her right hip, and on or about February 19, 2010, Ms. White had the DePuy ASR implanted into her left hip. The implants should have lasted at least fifteen (15) years.

58. Tests of Barbara White's blood performed during a follow-up visit with her physician in February 2012 revealed that her blood had been contaminated with high levels of chromium and cobalt.

59. Due to the results, the decision was made to monitor Plaintiff Barbara White's blood for a period of six month and at that time perform additional testing of Plaintiff's blood.

60. Following the February 2012 blood testing, additional tests of Barbara White's blood were performed in September 2012, revealing that her blood was contaminated with even higher levels of chromium and cobalt from just six months prior and well above acceptable levels.

61. Exposure to these toxic metals in Ms. White's blood have subjected her to an significantly increased risk of future injury and disease, including neurological injuries and cancer.

62. A sonogram was also taken in August 2012, revealing that a soft tissue mass was starting to form around the right hip implant.

63. The results of the blood tests and sonogram led to the recommendation by Ms. White's treating physician to undergo revision surgery.

64. Plaintiff Barbara White underwent revision surgery on her left hip on November 15, 2012, and revision and replacement surgery on her right hip on March 11, 2013.

65. In addition to the multiple risks attendant to surgery, e.g., infections, etc., the revision and replacement surgeries also required Ms. White to undergo additional rehabilitation.

66. Prior to Plaintiff Barbara White's implantation surgery, she was energetic with an active lifestyle. Her injuries due to the defective DePuy ASR have caused significant harm and rendered her unable to conduct many ordinary functions as well as make impossible her participation in physical activities she previously enjoyed.

67. As a further result, Plaintiff Barbara White has suffered physical pain and suffering, emotional distress, and a loss of life's pleasures and her sense of well-being, all of which are, or will be, permanent.

68. In reliance on DePuy's marketing of the DePuy ASR, Plaintiff Barbara White and her physician expected that the DePuy ASR would provide her with better stability and range of motion than other hip replacement devices on the

market. In addition, Ms. White's physician believed that the DePuy ASR would last her for significantly longer, and Ms. White expected a significant improvement in her quality of life after the initial hip replacement surgeries, which did not occur.

69. Plaintiff Barbara White's husband, Patrick White, has also suffered from the loss of her companionship, services, love, society, and affection.

70. As a result of the physical injuries, and risk of future disease and injury that Ms. White has incurred due to Defendants' culpable acts and omissions, Plaintiff Barbara White has been and will continue to be required to expend money on medical treatment and medical surveillance, and has suffered other economic damages, all of which are or may be permanent.

COUNT I
Strict Liability – Failure to Warn and Instruct

71. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

72. At all relevant times hereto, Defendants were engaged in the design, development, testing, manufacturing, marketing promotion and sales of the DePuy ASR. Defendants designed, manufactured, assembled and sold the DePuy ASR to medical professionals and patients knowing that they would be implanted in patients in need of hip prosthesis.

73. Defendants distributed and sold the DePuy ASR in the condition in which it left its place of manufacture, in its original form of manufacture, which included the defects described herein. The DePuy ASR was expected to, and did reach Plaintiff Barbara White without substantial change or adjustment in its condition as manufactured and sold by Defendants.

74. The DePuy ASR designed, developed, tested, manufactured, marketed and sold or otherwise placed into the stream of commerce by Defendants was in a dangerous and defective condition and posed a threat to any user or consumer of the DePuy ASR. Plaintiff was, and is, in a class of persons that Defendants should have considered to be subject to the harm caused by the defective nature of the DePuy ASR.

75. The DePuy ASR was implanted and used in the manner for which it was intended. This use has resulted in severe physical and emotional and other injuries to Plaintiff Barbara White.

76. Defendants knew or should have known through testing, adverse event reporting, or otherwise, that the DePuy ASR created a high risk of bodily injury and serious harm,

77. Defendants failed to provide adequate and timely warnings or instructions regarding the DePuy ASR and its known defects.

78. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff Barbara White has sustained, and will continue to sustain, severe physical injuries, severe emotional distress, mental anguish, economic losses and other damages. As a direct result of Defendants' wrongful conduct Plaintiff expended large sums of money and will continue to expend money for medical expenses. Plaintiff is entitled to compensatory damages in an amount to be proven at trial.

COUNT II
(Strict Liability – Design Defect)

79. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

80. Defendants are the manufacturer and/or supplier of the DePuy ASR and placed this device into the stream of commerce in a defective and unreasonably dangerous condition such that the foreseeable risks exceeded the benefits associated with the design and/or formulation of the DePuy ASR.

81. The DePuy ASR manufactured, marketed, distributed and/or supplied by Defendants was defective in design or formulation in that, when the medical device left the hands of the manufacturers and/or suppliers, the foreseeable risks exceeded the benefits associated with the design or formulation.

82. The DePuy ASR was expected to and did reach Plaintiff Barbara White without substantial change in condition. Alternatively, the DePuy ASR

manufactured and/or supplied by Defendants was defective in design or formulation, because when the DePuy ASR device left the hands of Defendants, the manufacturers and/or suppliers, the DePuy ASR was unreasonably dangerous and more dangerous than an ordinary consumer would expect.

83. The DePuy ASR manufactured and/or supplied by Defendants was defective due to inadequate warnings and/or inadequate trials, testing and study, inadequate exposure of the real risks inherent with the drug as determined by the clinical trials, and inadequate reporting of the results of the clinical trials and post-marketing clinical experiences with the device.

84. The DePuy ASR manufactured and/or supplied by Defendants was defective due to inadequate post-marketing warnings or instructions because, after Defendants knew or had reason to know of the risk of injury from the DePuy ASR, it failed to provide adequate warnings to the medical community, patients, and the public, including Plaintiff, and continued to promote and advertise the DePuy ASR as safe and effective.

85. The DePuy ASR was designed, manufactured, distributed, tested, sold, marketed, and advertised defectively by Defendants. As a direct and proximate cause of Defendants' defective design of the DePuy ASR, Plaintiff Barbara White and other patients had the device implanted in their bodies, and

suffered and will continue to suffer increased risk of long-term complications and pain and additional surgeries, personal injuries, the need for corrective surgery, and pain and suffering.

86. Defendants were or should have been in possession of evidence demonstrating that the DePuy ASR caused serious injuries and would fail. Nevertheless, Defendants continued to market the device by providing false and misleading information with regard to the safety and efficacy of the DePuy ASR.

87. Defendants' actions, as described above, were performed willfully, intentionally and with reckless disregard for the rights of Plaintiff, other patients and the public.

88. As a result of Defendants' conduct, Plaintiff Barbara White suffered losses, injuries and damages specified herein.

COUNT III
(Strict Liability – Manufacturing Defect and Failure to Adhere to Quality Controls)

89. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

90. The DePuy ASR is defectively manufactured because the foreseeable risks of mechanical malfunction and failure outweigh the benefits associated with the DePuy ASR.

91. The DePuy ASR was expected to and did reach the Plaintiff Barbara White without substantial change or adjustment to its mechanical function.

92. Defendants knew or should have known of the manufacturing defects and the risk of serious bodily injury that exceeded the benefits associated with the DePuy ASR.

93. Furthermore, the DePuy ASR and its defects presented an unreasonably dangerous risk beyond what the ordinary consumer would reasonably expect.

94. The DePuy ASR was defective due to inadequate warnings or instruction because Defendants knew or should have known that the DePuy ASR created a high risk of bodily injury and serious harm. Defendants failed to adequately and timely warn consumers of this risk.

95. The DePuy ASR is inherently dangerous for its intended use due to a manufacturing defect or defects and improper functioning. Defendants are therefore strictly liable to Plaintiff for their breach of duty to Plaintiff.

96. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff Barbara White has sustained and will continue to sustain severe physical injuries, and Plaintiff has suffered and will continue to suffer severe emotional

distress, mental anguish, economic losses and other damages for which she is entitled to compensatory damages in an amount to be proven at trial.

COUNT IV
(Negligence)

97. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

98. At all relevant times, Defendants had a duty and continue to owe a duty to Plaintiff Barbara White to provide a safely manufactured product, to notify the FDA of flaws, and to warn the FDA and Plaintiff of the defective nature of the DePuy ASR.

99. Defendants breached their duty of reasonable care to Ms. White by defectively designing, manufacturing, and/or negligently failing to warn of these defects in the DePuy ASR, thereby causing Plaintiff's injuries and damages.

100. Defendants breached their duty of reasonable care to Ms. White by manufacturing and assembling the DePuy ASR in such a manner that it was prone to failures and malfunction and thus exposed Plaintiff to severe and lasting physical trauma and injuries.

101. Defendants breached their duty of reasonable care to Ms. White by failing to promptly and adequately notify the FDA and warn and instruct Plaintiff,

the medical community, and the public at the earliest possible date of known defects in the DePuy ASR.

102. Defendants breached their duty of reasonable care to Ms. White by failing to exercise due care under the circumstances.

103. As a direct and proximate result of Defendants' wrongful misconduct, Plaintiff Barbara White has sustained and will continue to sustain severe physical injuries, severe emotional distress, mental anguish, economic losses and other damages for which she is to compensatory and equitable damages in an amount to be proven at trial.

COUNT V
(Negligence Per Se)

104. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

105. Defendants have an obligation to not violate the law in the manufacture, design, testing, assembly, inspection, labeling, packaging, supplying, marketing, selling, advertising, preparing for use, warning of the risks and dangers of the DePuy ASR, and otherwise distributing the DePuy ASR.

106. Defendants' acts and omissions constitute an adulteration, misbranding, or both, as defined by the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 331(a) and 333(a)(2), and constitute a breach of duty subjecting

Defendants to civil liability for all damages arising therefrom, under theories of negligence *per se*.

107. Plaintiff Barbara White, as a purchaser of the DePuy ASR, is within the class of persons the statutes and regulations (described above) are designed to protect and Plaintiff's injuries are the type of harm these statutes and regulations are designed to prevent.

108. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff Barbara White has sustained and will continue to sustain severe physical injuries, severe emotional distress, mental anguish, economic losses and other damages for which she is entitled to compensatory and equitable damages in an amount to be proven at trial.

COUNT VI
(Breach of Implied Warranty)

109. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

110. Defendants impliedly warranted that the DePuy ASR, which Defendants designed, manufactured, assembled, promoted and sold to Plaintiff and their physicians, was merchantable and fit and safe for ordinary use.

111. Defendants further impliedly warranted that the DePuy ASR, which Defendants designed, manufactured, assembled, promoted and sold to Ms. White

and her physicians, was fit for the particular purposes for which it was intended and was sold.

112. Contrary to these implied warranties, the DePuy ASR was defective, merchantable, and unfit for its ordinary use when sold, and unfit for the particular purpose. for which it was sold.

113. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff Barbara White has sustained and will continue to sustain severe physical injuries, severe emotional. distress, mental anguish, economic losses and other damages for which she is entitled to compensatory and equitable damages in an amount to be proven at trial.

COUNT VII
(Breach Of Express Warranty)

114. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

115. Defendants expressly warranted to Plaintiff Barbara White by and through Defendants, and/or their authorized agents or sales representatives, in publications, package inserts, the internet, and other communications intended for physicians, patients, Plaintiff, and the general public, that the DePuy ASR was safe, effective, fit and proper for its intended use.

116. Defendants also described the DePuy ASR as a "high performance hip replacement" and advertised it with pictures of a young woman running on a sandy beach, and a man taking a very aggressive golf swing.

117. In allowing the implantation of the DePuy ASR, Plaintiff and her physician relied on the skill, judgment, representations, and express warranties of Defendants. These warranties and representations were false in that the DePuy ASR was not safe and was unfit for the uses for which it was intended.

118. Through sale of the DePuy ASR, Defendants are merchants pursuant to Section 2-314 of the Uniform Commercial Code.

119. Defendants breached their warranty of the mechanical soundness of the DePuy ASR by continuing sales and marketing campaigns highlighting the safety and efficacy of their product, while they knew of the defects and risk of product failure and resulting patient injuries,

120. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff Barbara White has sustained and will continue to sustain severe physical injuries, severe emotional distress, mental anguish, economic losses and other damages for which she is entitled to compensatory and equitable damages in an amount to be proven at trial.

COUNT VIII
(Negligent Misrepresentation)

121. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

122. At the time Defendants manufactured, designed, marketed, sold and distributed the DePuy ASR for use by Plaintiff Barbara White, Defendants knew or should have known of the use for which the DePuy ASR was intended and the serious risks and dangers associated with such use of the DePuy ASRs.

123. Defendants owed a duty to treating physicians and to the ultimate end-users of the DePuy ASR, Plaintiff, to accurately and truthfully represent the risks of the DePuy ASR, Defendants breached that duty by misrepresenting and/or failing to adequately warn Plaintiff's physicians, the medical community, Plaintiff, and the public about the risks of the DePuy ASR, which Defendants knew or in the exercise of diligence should have known.

124. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff Barbara White sustained and will continue to sustain severe physical injuries, severe emotional distress, mental anguish, economic losses and other damages for which she is entitled to compensatory damages in an amount to be proven at trial.

COUNT IX
(Loss of Consortium)

125. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

126. At all relevant times hereto, Plaintiff Barbara White was married to her spouse, Patrick White, who has suffered injuries and losses as a result of Defendants' wrongful conduct.

127. For the reasons set forth herein, Plaintiff Patrick White has necessarily paid and has become liable to pay for medical expenditures and will necessarily incur further expenses of a similar nature in the future as a proximate result of Defendants' misconduct.

128. For the reasons set forth herein, Plaintiff Patrick White has suffered and will continue to suffer the loss of his beloved wife's support, companionship, services, society, love and affection.

129. Plaintiff Patrick White alleges his marital relationship with Barbara White has been impaired and depreciated, and the marital association between husband and wife has been damaged and altered.

130. Plaintiff Patrick White has suffered emotional pain as a direct and proximate result of the injuries to his wife.

131. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff Patrick White has sustained and will continue to sustain severe emotional distress, economic losses and other damages for which he is entitled to compensatory and equitable damages in an amount to be proven at trial. Defendants are liable to Plaintiff Patrick White for all general, special and equitable relief to which he is entitled by law.

COUNT X
(Unjust Enrichment)

132. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

133. As the intended and expected result of their conscious wrongdoing, Defendants have profited and benefited from the purchase of Defendants' DePuy ASR by Plaintiffs Barbara White and Patrick White.

134. Defendants have voluntarily accepted and retained these profits and benefits, derived from Plaintiffs Barbara White and Patrick White, with full knowledge and awareness that, as a result of Defendants' fraud and other conscious and intentional wrongdoing, Plaintiffs Barbara White and Patrick White were not receiving a product of the quality, nature or fitness that had been represented by Defendants or that Plaintiffs Barbara White and Patrick White, as reasonable consumers, expected.

135. By virtue of the conscious wrongdoing alleged above, Defendants have been unjustly enriched at the expense of Plaintiffs Barbara White and Patrick White, who are entitled to in equity, and hereby seek, the disgorgement and restitution of Defendants' wrongful profits, revenues and benefits, to the extent and in the amount deemed appropriate by the Court; and such other relief as the Court deems just and proper to remedy the Defendants' unjust enrichment.

COUNT XI
(Punitive Damages)

136. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

137. The acts of Defendants were willful and wanton, malicious, and showed a total disregard for Plaintiff Barbara White's rights and well-being, and for human life and human suffering. Defendants knew or knowingly and recklessly disregarded facts which made it evident that their conduct would naturally and probably result in injury and damage. Defendants' course of conduct warrants an award of punitive damages.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment against Defendants as follows:

A. Economic and non-economic damages;

B. Compensatory damages;

C. Punitive damages;

D. Such interest, fees and costs such as are allowed by law; and,

E. Such other and further relief as the Court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiffs demand a jury trial on all claims so triable.

Respectfully submitted,

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